

### **REMARKS/ARGUMENTS**

The following remarks are submitted in response to the Office Action of January 31, 2008, in which claims 1-22, 25-70 and 73-75 are pending, claims 28-56 are withdrawn from consideration, claims 1-22, 25-27, 57-70 and 73 are rejected and claims 74-75 are allowed. Reconsideration, examination and allowance of all pending claims are respectfully requested.

#### **Claim Rejections Under 35 U.S.C. §103**

Claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, and 73 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Ren et al.*, U.S. Patent 6,045,547 (hereinafter “Ren”), in view of *Viera*, U.S. Patent 6,039,699. Applicants respectfully traverse this rejection. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.

The Examiner correctly notes, in paragraph 7 of the Office Action, that “the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” However, in the instant claims, the claimed product, because of the process recited in the product-by-process claims, is different from the products of the prior art.

Ren is cited for discloses a multi-layer catheter tube having layers with differing stiffnesses. Viera is cited for teaching a multi-layer guidewire where each of the inner and outer layers are made of metal. Viera teaches that the outer layer, sleeve 340, may be secured to the inner layer, corewire 320, “with an adhesive, for example, or may be welded, brazed, or soldered, for example, to corewire 320.” Col. 4, ll. 26-30. These are ways of securing the two layers which are commonly done only at the two ends of the shorter layer (in this case, the outer layer).

In contrast, claim 1, for example, recites “a composite medical device produced by a process comprising constructing a composite elongate shaft by *forming* a metallic outer portion comprising a first metallic material about a metallic inner portion.” As taught in the specification, such forming of one layer about another creates a composite shaft of unitary construction. Specification, page 8, lines 23-29. A composite is a material made of distinct

components, such as fiberglass. Here, the composite material of the shaft is created by forming one layer about another. Such a process creates the composite by forming a metallic bond between the two layers along the length of the shaft. This metallic bond is a structural difference between the claimed invention and the cited prior art, and is not taught or suggested by the prior art.

Because independent claims 57 and 73 each recite “a composite shaft,” applicant submits that these claims are in condition for allowance for the reasons discussed above. Because claims 9, 11, 13, 15, 16, 18-21, 25-26, 59, 61, 63-64 and 66-68 depend, directly or indirectly, from one of claims 1 and 57 and contain additional elements, applicants submit that these claims are in condition for allowance as well.

In the September 27, 2007 Office Action, claims 6 and 7 were rejected based on Ren’s teaching of a method of making its multilayer polymeric catheter tube by using an extruder having a co-extrusion head. (Claims 6 and 7 are directed to co-drawing or co-extruding the inner and outer portions to produce the composite shaft.) However, the catheter tube of Ren is polymeric and Ren does not teach metal processing methods. Where Ren teaches components that may be metal (wire braid in col. 3, l. 15; core wire in col. 5, l. 5), Ren is silent as to manufacturing methods. If a person of skill in the art were, for the sake of argument, to look at Ren and Viera and then decide to make a multi-layer metallic catheter tube, the person of skill in the art would not look to the polymer processing techniques of Ren to make a metal tube.

A person of skill in the art understands that polymers and metals are processed using very different techniques. Though the term extrusion is used with respect to both a polymer processing technique and a metal process technique, the polymer extrusion process is very different from the metal extrusion process. One basic, key difference is that polymers are extruded in a molten state and metals are extruded in a solid state and under much higher pressure. Another difference is that in a polymeric coextrusion process as described by Ren, material selection, a tie layer and heat can be relied upon to make a bond between layers. This is not the case in a metal extrusion process. Because the metal is not heated to a molten state, pressure, forcing the layers together, is important to make a bond to form a composite material.

Thus, one of skill in the art looking to replicate the Ren catheter in metal would look to the metal processing techniques discussed in Ren, where the two layers are formed separately and then joined using an adhesive, welding, brazing or soldering technique. Because neither reference teaches a metal co-extrusion process or a co-drawing process, applicant respectfully submits that all claim elements have not been taught or suggested and that no prima facie case of obviousness has been established.

### Conclusion

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance, and issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his attorney,

Date: \_\_\_\_\_

March 31, 2008

  
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